CHARGE: 502(a)—the labeling of the article, while held for sale, namely, the label of the repackaged article, contained false and misleading representations that the article was an adequate and effective treatment for diabetes; that the article was effective in the prevention and treatment of high blood pressure and hardening of the arteries; that it would keep the blood cells and body tissues youthful; and that it would enable the body to resist infection.

DISPOSITION: On 8–12–57, John Wolf, claimant, filed exceptions to the libel; and, on 10–3–57, the exceptions were denied. On 4–23–58, on motion of both parties to the libel action, judgment of condemnation was entered and the court ordered that the product be destroyed.

5480. 3N liniment. (F.D.C. No. 40133. S. No. 57–190 M.)

QUANTITY: 984 4-oz. btls. and 1 5-gal. btl. at Cedartown, Ga., in possession of Colston's Sales Co.

SHIPPED: 6–26–56 and 2–13–57, from Chattanooga, Tenn.

LABEL IN PART: (4-oz. btl.) "3N Liniment * * * Active Ingredients: Camphor, Capsicum, Citronella, Cajeput, Spikenard, Castor Oil, Alkanet, Isopropyl Alcohol 80–85 percent * * * 4 Fluid Ounces Price $1.35 Distributed by Colston's Sales Co., 230 3rd Street, Cedartown, Georgia."

ACCOMPANYING LABELING: Leaflets entitled "Directions For The Use of 3N Liniment" and "3N Liniment Reg. U.S. Pat. Office."

RESULTS OF INVESTIGATION: The leaflets were printed at the direction of the dealer.

LIBELED: 4–10–57, N. Dist. Ga.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for rheumatism, arthritis, neuritis, lumbago, deep pains, and "other things where a pain or germ killer is needed."

DISPOSITION: 10–28–57. Consent—claimed by Colston's Sales Co. and relabeled.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 5461 TO 5480

PRODUCTS

[1] (5479) Seizure contested.

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5481–5500

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings terminated upon pleas of guilty; and (3) injunction proceedings in which decrees of injunction were entered with the consent of the parties, or after default. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., May 27, 1959.

CONTENTS*

*For presence of a habit-forming substance without warning statement, see No. 5485; omission of, or unsatisfactory, ingredients statements, Nos. 5485, 5486; sale under name of another drug, No. 5481; failure to bear a label containing an accurate statement of the quantity of the contents, No. 5486; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 5486, 5487.

504893—59——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 5481–5500

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and its strength differed from, and its quality and purity fell below, the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength and quality differed from that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol, and the name, and quantity or proportion of atropine, hyoscine, and hyoscyamine contained therein; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(g), the article purported to be a drug, the name of which is recognized in an official compendium (United States Pharmacopeia), and it was not packaged as prescribed therein; Section 502(i)(3), the article was a drug offered for sale under the name of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in the labeling; Section 502(l)(2), the article was, or purported to be, or was represented as, a drug composed wholly or partly of penicillin; and it was from a batch with respect to which a certificate issued pursuant to Section 507 was not in effect; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

5481. Castor oil and hydrogen peroxide solution. (F.D.C. No. 40474. S. Nos. 24–038 M, 50–722 M, 50–821 M.)

INFORMATION FILED: 2–10–58, S. Dist. Calif., against Norton Chemical Co., Inc., t/a Norton Products Co., Los Angeles, Calif.

ALLEGED VIOLATION: During the year of 1956, while a quantity of turpentine was being held for sale at Los Angeles, Calif., after shipment in interstate commerce, the defendant caused the turpentine to be repacked into bottles labeled,